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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,663	06/21/2006	Joachim Fensterle	281782US0PCT	7224
22850	7590	04/15/2009	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			04/15/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/559,663	<b>Applicant(s)</b> FENSTERLE ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-12,14,15 and 17-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-12,14,15 and 17-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 15 January 2009, is acknowledged.

Claims 1, 9, 12, 17 and 18 have been amended. New claims 29-40 have been added.

2. Claims 1-4, 6-12, 14, 15 and 17-40 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of cells, is withdrawn in light of the amendment of the claim.

4. The rejection of claims 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for "foreign", is withdrawn in light of the amendment of the claims.

5. The rejection of claims 1-4, 6-8, and 19 under 35 U.S.C. 102(b) as being anticipated by Curtiss et al (U.S. Pat. No. 6,383,496) is withdrawn in light of the amendment of the claims.

6. The rejection of claims 1-4, 6-8, and 19 under 35 U.S.C. 102(b) as being anticipated by Curtiss et al (U.S. Pat. No. 6,024,961) is withdrawn in light of the amendment of the claims.

### **Rejections Maintained**

7. The rejection of claims 9-12, 14, 15, and 17-18 under 35 U.S.C. 112, first paragraph, scope of enablement for methods of treatment of disorders, is maintained for reasons of record.

Applicants argue that bacteria delivered into the tumor system have active enzyme and that the bacteria are enriched in the tumor tissue. The product of the enzyme conversion of the prodrug is known to be toxic to tumor cells and the combined effect of the enrichment in the tumor tissue and successful conversion is directly correlates to the efficacy.

The examiner has considered applicants' arguments, but does not find them persuasive. While the data supplied by applicants indicate that the transgenic bacteria are present in tumor tissue and that tumor lysates have the ability to form relative amounts of MeP from the

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substrate MePdR, the data show no actual tumor regression following treatment with the *L. Monocytogenes* delta aroA to which the claims are directed.

8. The rejection of claims 20-28 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is

### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4, 6-12, 14, 15 and 17-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 1 is now drawn to an isolated mammalian cell loaded with a recombinant bacteria and "the isolated mammalian cell is capable of prophylaxis or therapy of neoplastic diseases in a subject".

Because the qualifier does not recite that the "loaded" mammalian cell is capable of prophylaxis or therapy of neoplastic diseases in a subject, it is uncertain if the mammalian cell has the capability or if only the "loaded" cell has the claimed capability.

Claims 2-4, 6-12, 14, 15 and 17-40 depend from claim 1, but do not clarify the issue.

### **Conclusion**

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 10, 2009